milligrams in 24 hours. Infants 4 months to under 2 years of age: oral dosage is 0.313 milligram every 4 to 6 hours, not to exceed 1.252 milligrams in 24 hours.

(r) *For products containing diphenhydramine citrate identified in § 341.14(a)(5).* Children 2 to under 6 years of age: oral dosage is 9.5 milligrams every 4 hours, not to exceed 57 milligrams in 24 hours.

(s) *For products containing diphenhydramine hydrochloride identified in § 341.14(a)(6).* Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 4 hours, not to exceed 37.5 milligrams in 24 hours.

[51 FR 35339, Oct. 2, 1986, as amended at 52 FR 30057, Aug. 12, 1987; 54 FR 8509, Feb. 28, 1989; 57 FR 58376, Dec. 9, 1992; 59 FR 4218, Jan. 28, 1994; 59 FR 29174, June 3, 1994; 59 FR 36051, July 15, 1994]

PART 343—INTERNAL ANALGESIC, ANTIPYRETIC, AND ANTIRHEUMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

Subpart D—Testing Procedures

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 63 FR 56814, Oct. 23, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 343.1 Scope.

(a) An over-the-counter analgesic-antipyretic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 343.3 Definitions.

As used in this part:

Analgesic—antipyretic drug. An agent used to alleviate pain and to reduce fever.

Cardiovascular drug. An agent used to prevent ischemic events.

Rheumatologic drug. An agent used for the treatment of rheumatologic disorders.

Subpart B—Active Ingredients

§ 343.10 [Reserved]

§ 343.12 Cardiovascular active ingredients.

(a) Aspirin.

(b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in § 331.11 of this chapter provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in the United States Pharmacopeia 23/National Formulary 18.

§ 343.13 Rheumatologic active ingredients.

(a) Aspirin.

(b) Buffered aspirin. Aspirin identified in paragraph (a) of this section may be buffered with any antacid ingredient(s) identified in § 331.11 of this chapter provided that the finished product contains at least 1.9 milliequivalents of acid-neutralizing capacity per 325 milligrams of aspirin as measured by the procedure provided in